An Engineering Perspective on Quality

or

How to design a quality improvement that works and avoid "6x9 error"

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UC BIOMEDICAL ENGINEERING

Introductions and Warnings

- **Who**: An engineer with experience in several failed companies over time
  - General Motors, Xerox, Hughes Space and Communication, Reflectivity, ... , University of Canterbury (?)
  - Yet another lesson on association and causality?

- **What**: An experiential tour of how basic quality faults in process or design can kill your great new, actually good, idea ...

- **Warning**: I will avoid all the “stock” charts, processes, and buzzwords (if I can), and try to talk more about the basics from an engineering perspective
  - I.e. I promise not to solve your problem(s)

What is Quality?

- **Quality**: *noun* /kwälətē/: The standard of something as measured against other things of a similar kind; the degree of excellence of something

- Simple sense: does it perform well compared to similar things?
- Even simpler sense: is it good?

- **Main problem**: what do you compare against? How do you maintain quality? When do you compare? ...
  - Don’t we all have other jobs?
  - At Ford Motor Company “Quality is/was Job #1” ... But, is it really?

- **Other main problem**: how do you design an intervention that you are <u>confident</u> will perform better and <u>**stay that way**</u>?

UCBIOMEDICAL ENGINEERING

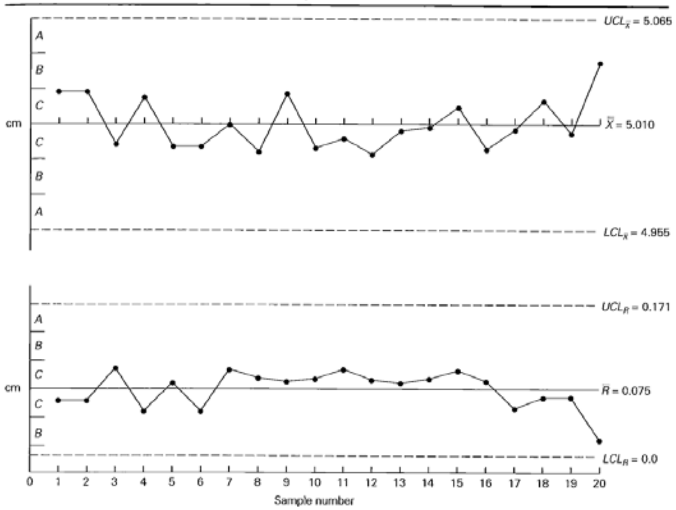
It's a way of thinking ... Not a recipe

- **Attention to detail**
- **Focus on critical elements**
- **Willingness to revisit the data regularly**
- **... OCD ... (?) ... Note that we haven't seen anything about charts or methods**
- **I.e. Cultural not methodological, but ..., then anyone can do it**

Assessing Quality

- Easy, and there about **<u>8 Trillion</u>** ways to do it … **(NB: statistic is entirely made up)**
  - Process control charts, run diagrams, X (averages) and R (ranges) charts, p-charts (proportion defective) ... None to different to Bland-Altman (over time) or others ...

EXHIBIT 4–23 $\bar{X}$ and R Charts: Injection-Molding Process



4–26 p Chart of Proportion of Defective Bills per Day

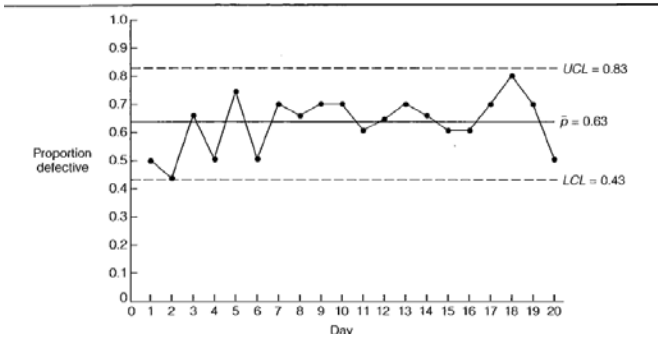
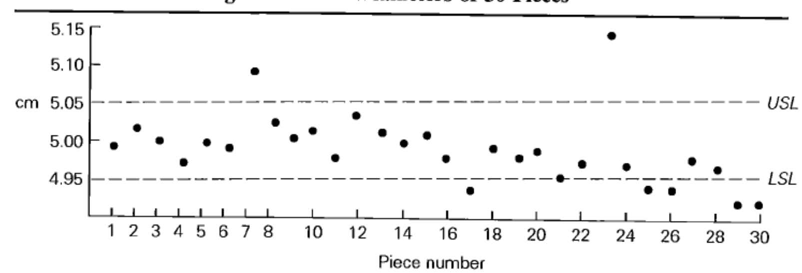


EXHIBIT 4–18 Run Diagram—Outer Diameters of 30 Pieces



- **Problem**: These are all after the fact ... They capture deviation from desired performance <u>and</u> improvement after a change, but, ... **They don't tell you whether a change is worth doing in the first place** ..

The real goal

- Design interventions to minimise risk of failing to improve
  - Means you should know, truly know, the answer before you implement it fully!
  - Assumes you are designing an improvement in care in the first place

- Main elements:
  - **Right metric**: something easy and non-arbitrary to measure
  - **Right metric**: make sure it isn't biased by admissions or other factors outside the control of the quality change
    - Means you need to understand those elements and what they might be
  - **Right metric**: something of value and relevance to the unit
    - Not typically financial, but workload, consistency of care, patient outcome, patient burden...

- Outcome: you need to define expected (and realistic) desired performance in design phase
  - Areas where you can get big changes are important, and areas where changes may be small or hard/arbitrary to measure may be less so.
  - Identifying these areas is actually the hard part

Metrics: the good, the bad, and the just plain ...

- **Good**:
  - BG, platelets, FiO2, mortality ... Deterministic, low error (except in South Africa?), measured regularly, easily identified and stratified, patient-centered …

- **Bad**:
  - LoMV, LoS, SMR, many agitation and acuity scores ... OK, but subject to uncontrolled bias in policy, cohort, admission process, time of day, patient type, ...
  - Cost, normally “good” but usually too broad a task. At GM we were always $800/car behind the Japanese and the constant demand to “reduce cost” wasn't helpful without a specific target. Note: “everywhere” is not a specific target.

- **The just plain ...** :
  - Effort (<u>not</u> related to countable tasks), perceived anything, in fact anything almost entirely subjective and based on personal feeling as it is very hard to get consistent results across a unit or cohort.

A real-life metric example

- Where to live metric (**WtL**):
  - WtL = Yearly_High_Temp – Yearly_Low_Temp
  - Here are two places that look the same, but are clearly different by metric – showing good resolution! The “sheep” are bigger in one too...

North Dakota = 42- (-45) = 87

Christchurch = 35 - (-4) = 39

Of course care must still be taken

- Care is needed with ideal values, so make sure you have all the necessary information in your metric

North Pole / Arctic = -5- (-40) = 35

San Francisco = 33 - (-2) = 35

- Perhaps average temp should be included!

Yeah, so ... ?

- Quality should come from a significant and in-depth design process <u>up front</u> (i.e. Think the idea through first)
  - There are actually very often only a few areas to improve quality and consistency in a realistic and sustainable manner (I could go on for hours ...)
  - Far fewer than are usually undertaken
  - Thus, as seen in my resume and a range of quality literature, many fail

- In many complex engineered products the design phase can be as long as, or longer than, the product lifecycle
  - Why should it be different in clinical cases?

- The reason?
  - Improving quality is easy, especially with extra resources available
  - Sustaining it is not, especially if extra resources are not available

- The solution ... design and careful targeting of quality improvements
  - *One sustained quality change is worth more than 1000 that are not* ...
  - A quote and statistic I just made up ... But reflective of the real outcomes
  - For example, almost every TGC protocol ever published (vs SPRINT)

Interestingly

- All those charts and process management systems are about measuring whether quality is sustained
- There is actually very little about how to design or target them

Leverage

- The biggest design improvements and game changers are at "leverage points" where big gains in cost/outcomes may be seen for relatively small changes in process, design or behaviour
  - GM designed a $125 ABS system when they cost $2500, where the big reduction leveraged ABS into 4x more cars (from top 20% to ~all)
  - Ipods/Iphones: leveraged low cost touch screens and good interface design into $500M per day of sales and whole new ways of accessing information
  - Winglets reduced fuel consumption in aircraft for a small change in design
- Note that all of these can be "defeated" by "poor" use of the device, or by poor construction.
  - Similarly, in healthcare, variability in how you implement something can reduce efficacy → <u>**good design comes in here**</u> to prevent that
  - Equally, variability in patient behaviour can defeat improvements targeted at the mean or median patient response. **Patients are variable too, the more conscious the more variable!**

3 Main Lessons

- *One Method* instead of *One Size* (fits all)
  - Most engineering areas design by a fixed “method” rather than a fixed answer or approach – they sound the same but ...

- Continual improvement **<u>is</u>** allowed, and in fact defines engineering ... Where nothing is so good that it cannot be “improved”
  - A real quote: ***There comes the time in the life of every project where it becomes necessary to shoot the engineers and begin production***

- Minimise your *6x9 error*
  - Design for easy assembly and for easy checking of mis-assembly

One Size Fits All

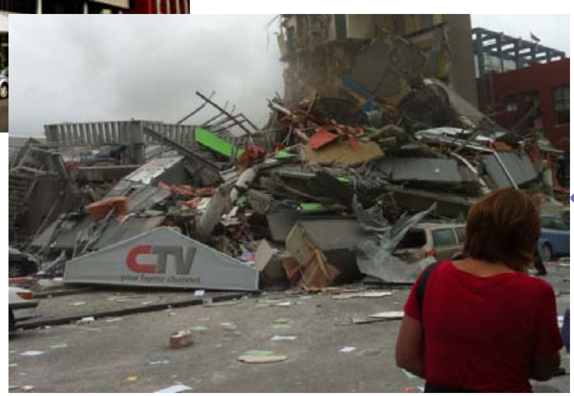
- **One Size**:
  - Based on a fixed rule or set of rules
  - Requires explicit calculations that are the same for the same inputs
  - **Risk**: rigid design that doesn't account for variable conditions or use
  - **Risk / Benefit?** Done once to get one answer, not iterative
  - **Benefit**: Ensures a minimum documentable standard (6ml/kg anyone?)
  - A “standard” in health care because easily documented and defended, and, to some, it removes the need for regular (<u>every</u> day) QC

I mentioned Civil Engineering

- Structural engineering codes are based on One Size approach to design and there is little QC in construction, despite some checking
  - ***Each is unique as they are built just once, but design is not!***

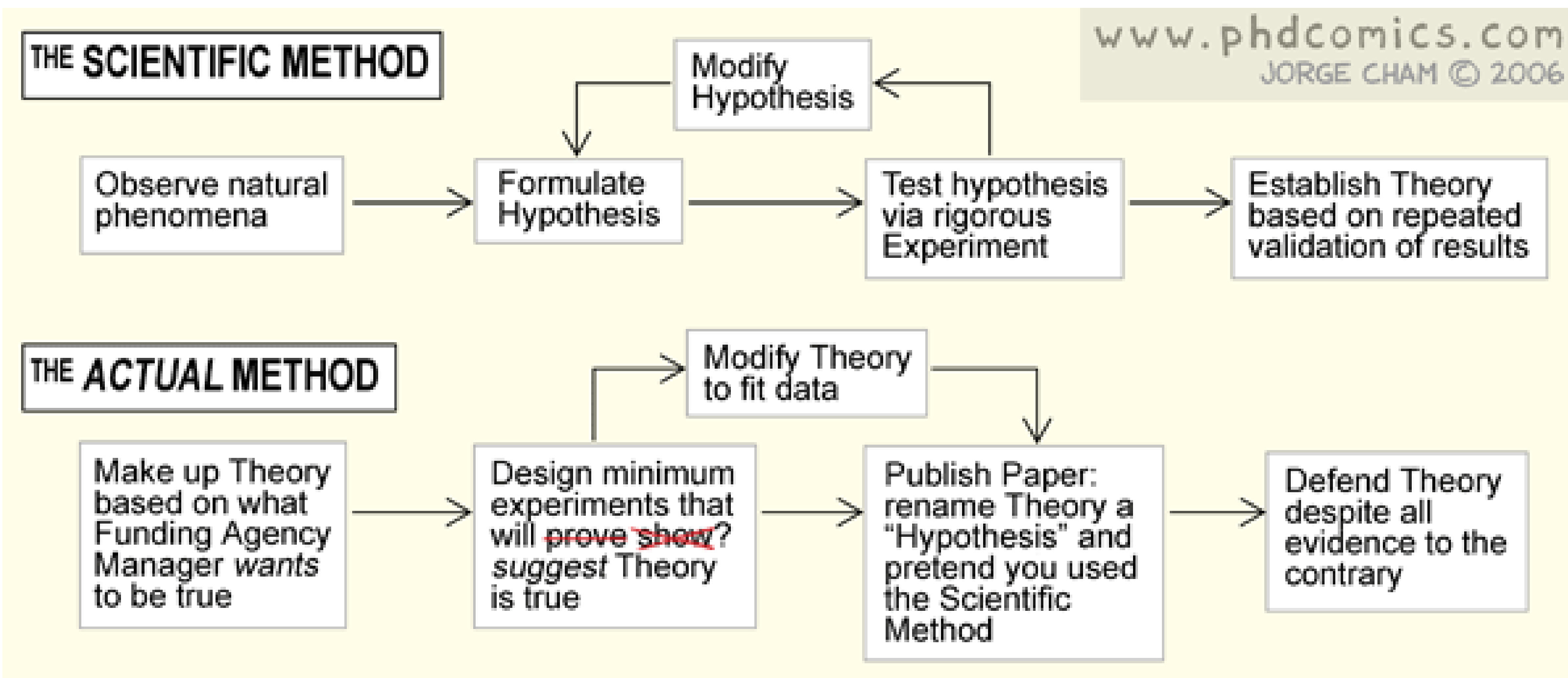
Didn't account for parking garage next door

Built to same code and in similar style – 3-5 blocks away



One Method Fits All

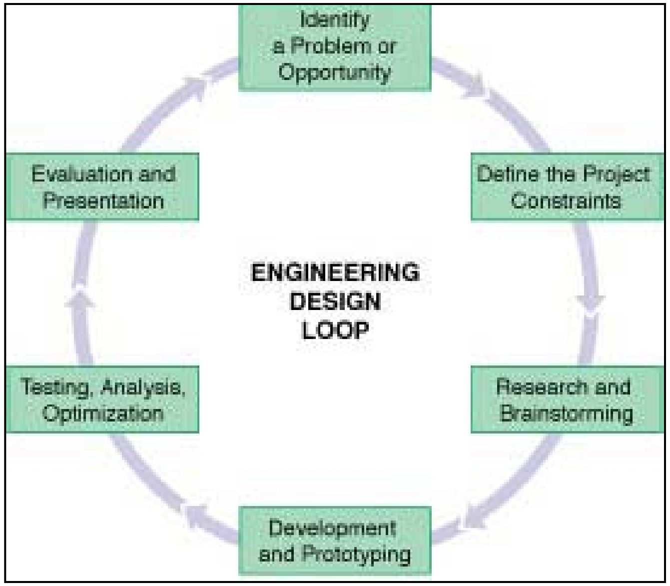
- **One Method**:
  - A fixed approach using models or other means to adapt design to specific conditions. Calculations are therefore not explicit, but <u>subject/product specific by method</u>
  - **Risk**: incorrect implementation → poor result and failure, hard to document!
  - **Benefit**: accounts for variability and changing conditions, individualised
  - **Benefit**: Inherently iterative in nature, always a chance and basis to improve
  - A “standard” in all arenas of engineering I have worked except Civil Eng, because you can use QC to check and easily ensure risks are minimised and benefits maximised.



Design

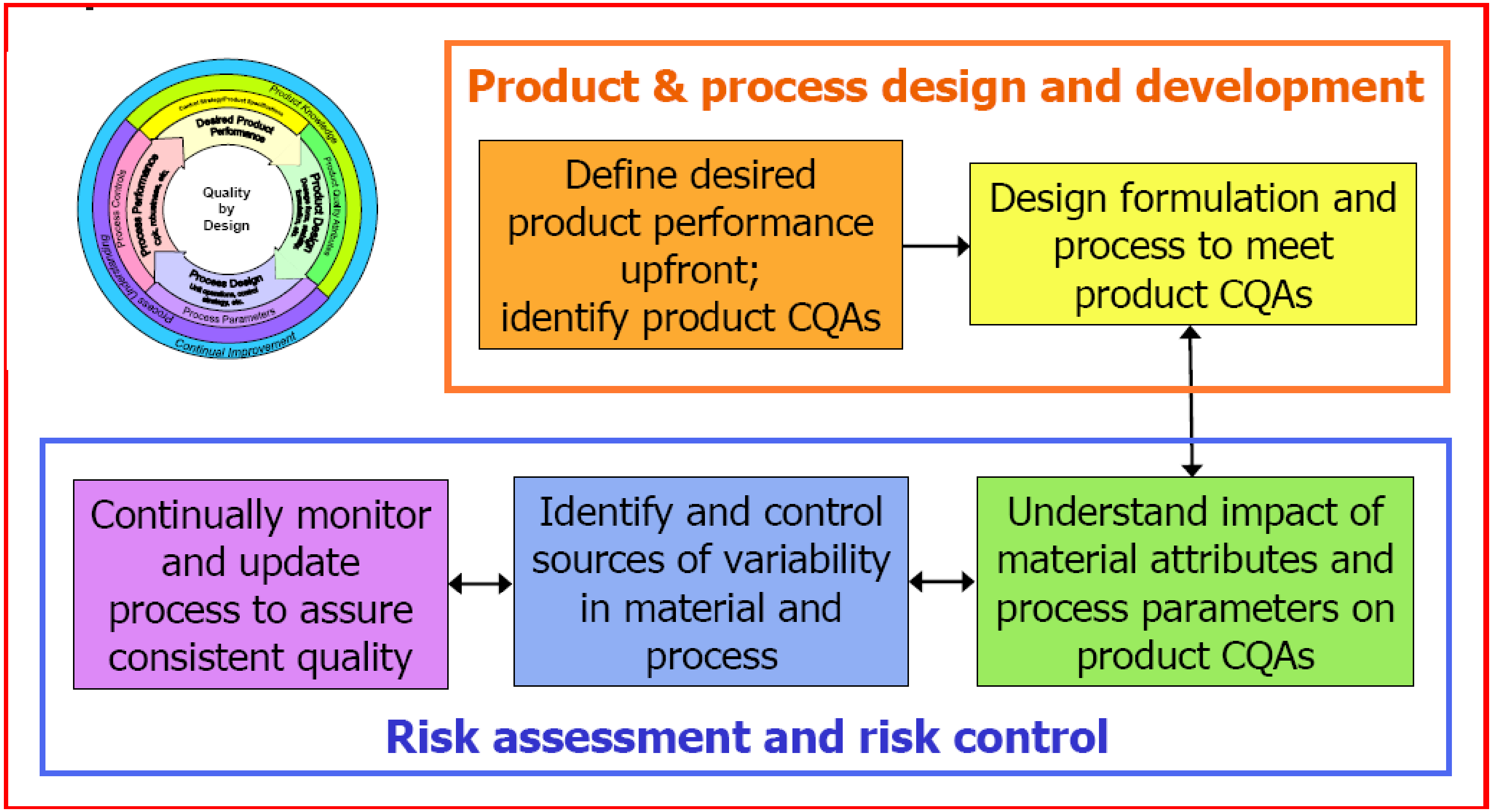
- 8 zillion ways to do it, but the fundamentals are always the same
  - **Information**
  - **Understanding**
  - **Not “outsiders”**

  - **Iterative development of solutions**
  - **Time consuming ~ Patience + Planning**
    - **Cars = 3-5 years or more**
    - **Medical devices = up to 10 years**
    - **Planes = up to 20 years**
    - **Computer chips = 2-4 years but ongoing**
    - **<u>Dedicated ongoing effort</u>**
  - We spent 5 years developing SPRINT
  - vs <6 months for other protocols (<1 week?)



Recently (re)discovered by the FDA!

- And given name Quality by Design (QbD)
  - For drug development primarily...



- **Source:** http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/ucm103453.pdf

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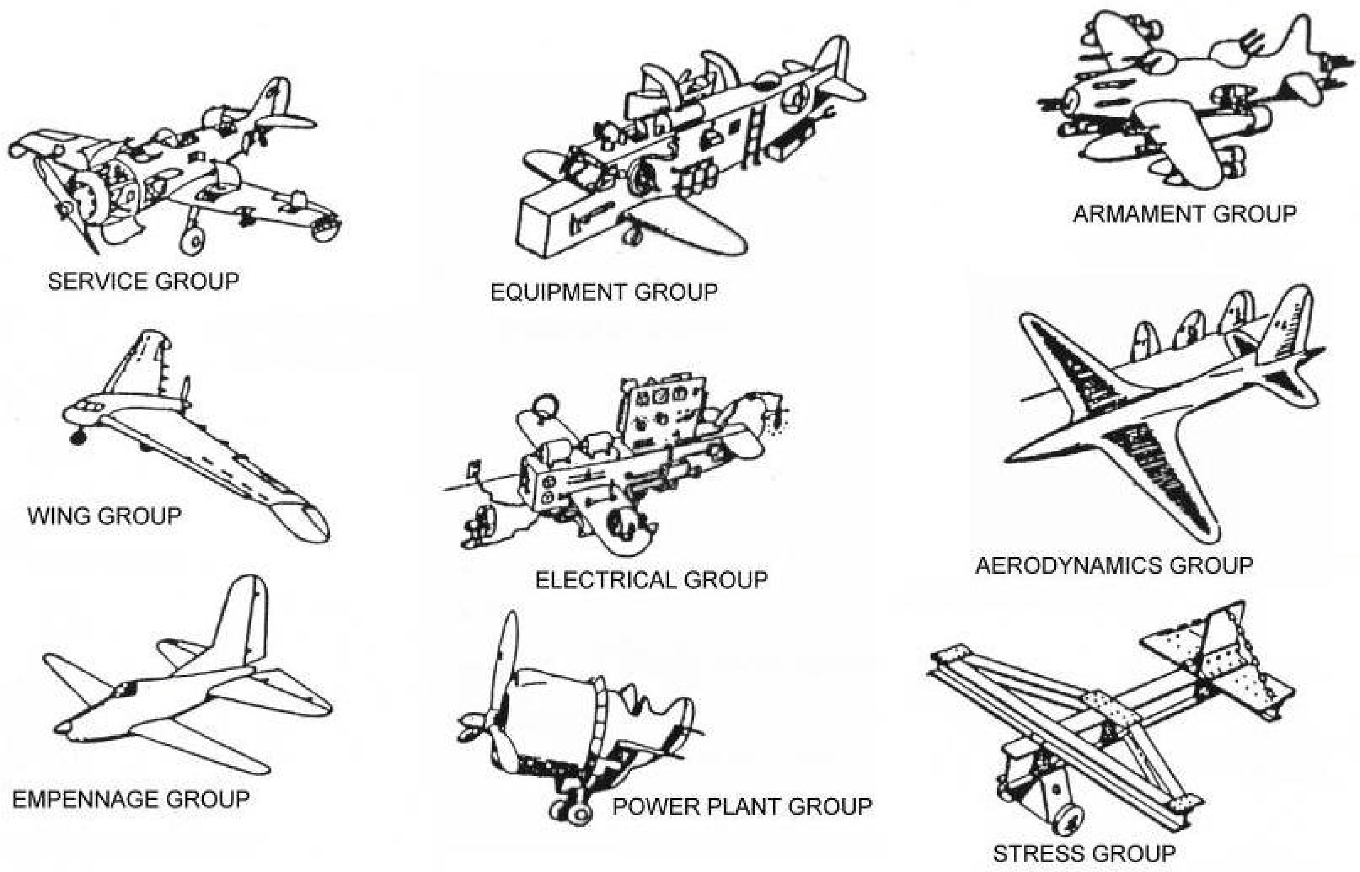
A note on design by committee

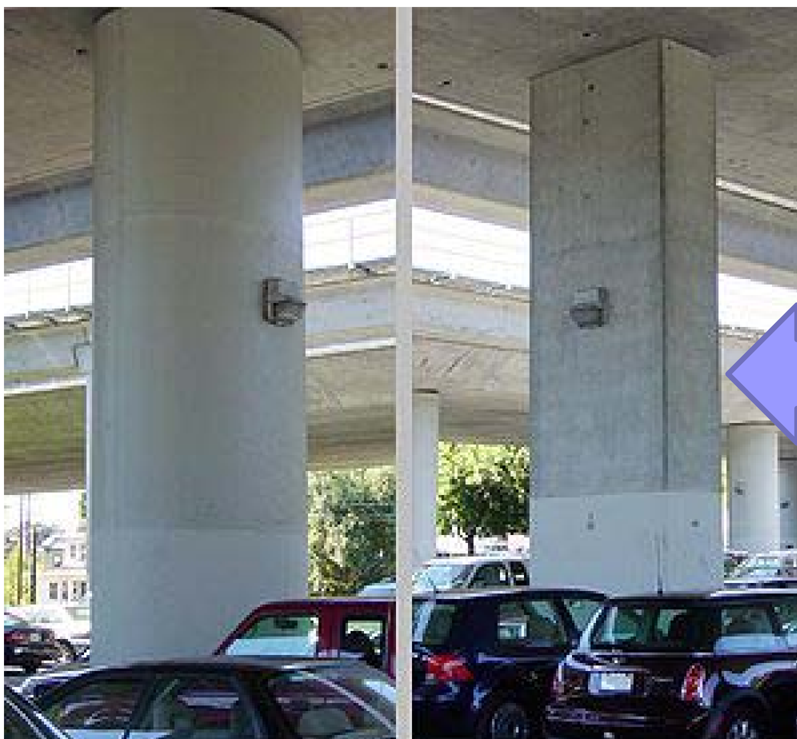
- Design does require leadership and focus
  - Preferably centered on end-users to avoid “strange perspectives”

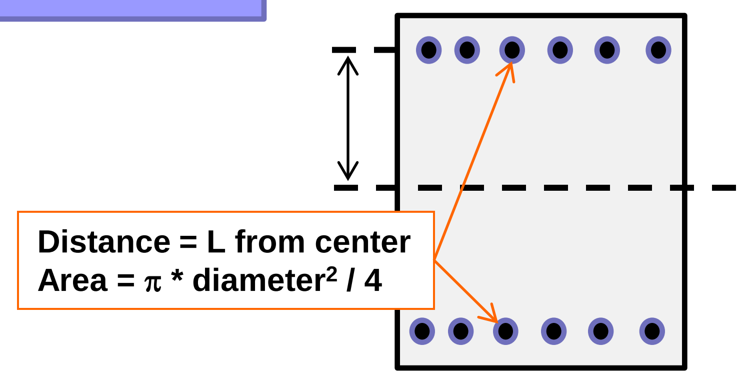


  - **<u>Nothing</u>** is worse than the resulting paralysis in large group design

6x9 Error – Implementation Matters

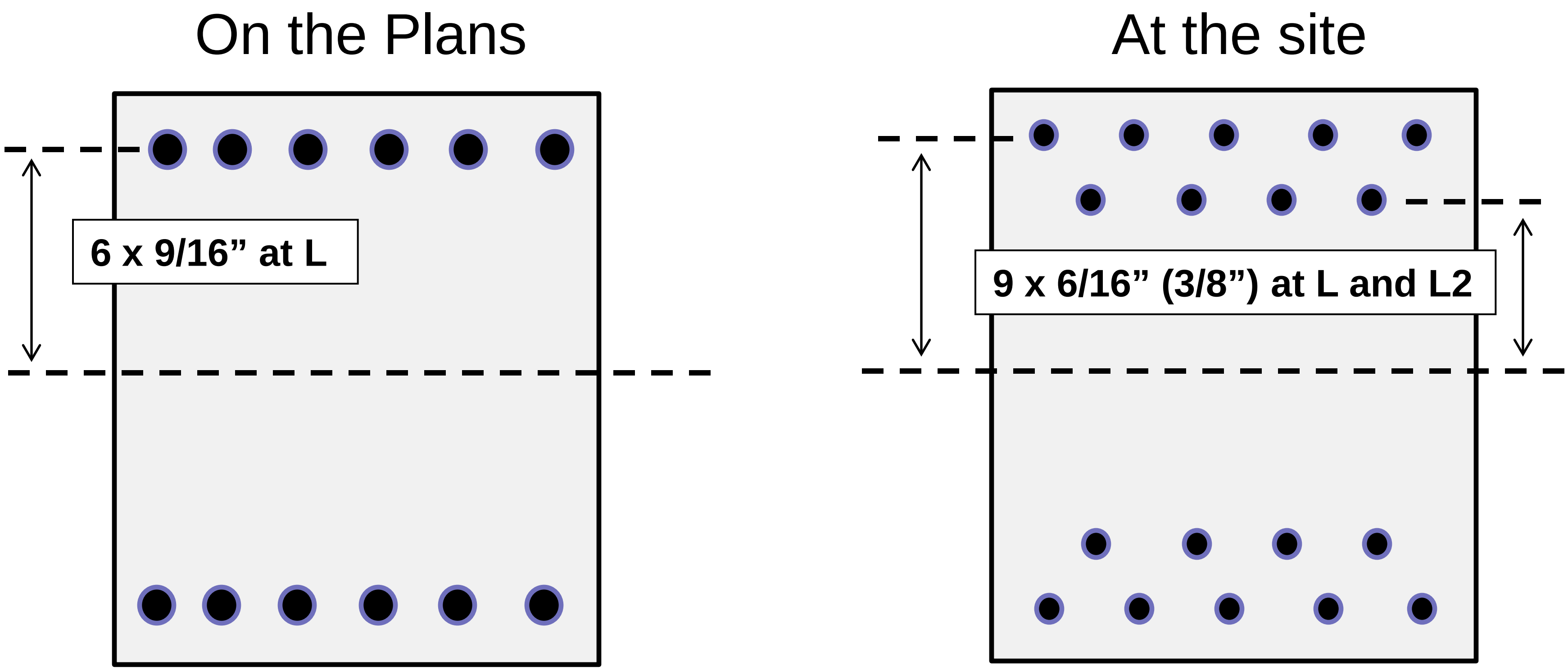
- Columns define a buildings strength and flexibility
- For steel reinforced concrete columns its the area or amount of steel, and the distance from the column center
  - More steel area and farther away is generally better





6x9 Error – Implementation Matters

- So, a young civil engineer is inspecting buildings in (city) in (recent year) and comes across ...



- The difference is **over 50% reduction** in stiffness and strength
  - PS: yes, this is bad ... Very (falling down) bad ...

6x9 Error – Implementation Matters

- Young 22 year old engineer vs 50+ year old Sr Foreman ...
  - What to do ?? ... Sound familiar?

- **Senior Foreman**: *Six 9s or nine 6s, same difference, and the 9/16ths is really hard to get these days* ...
- **Young Engineer**: *Ummmm* ...

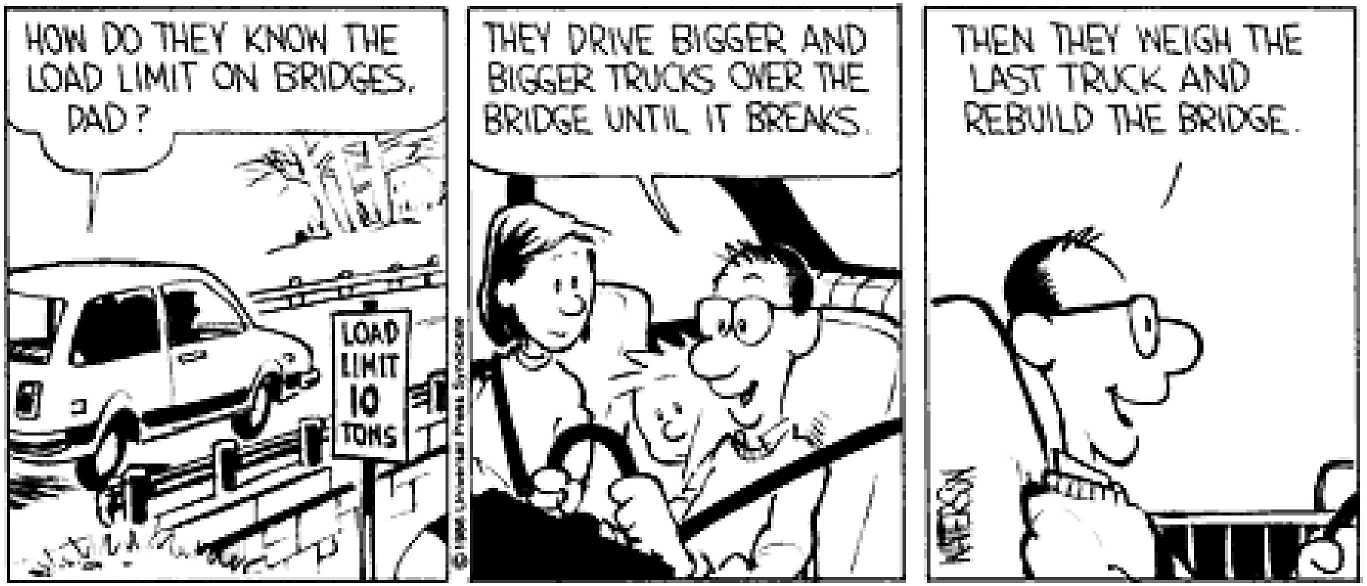
- **The Motto**: Never design something that isn't robust to how it might get built / implemented, your “6x9 error”
  - Never assume perfect implementation, especially if its complex
  - This limits a lot of otherwise feasible quality changes
  - <u>An improvement that adds effort isn't an improvement these days</u>
  - If you ask nicely I will tell you about “after lunch” cars ...

Design for Quality via Simplicity

- Keep it simple, but not too simple – every engineer knows this ... As do many other folks...
  - Yet, have you seen some of those protocol flow charts?!

And ...

- As with the previous slide ... It helps to **use good design to know the answer before you build it**...



- It will save you lots of time and effort, and all sorts of other good stuff

Summary?

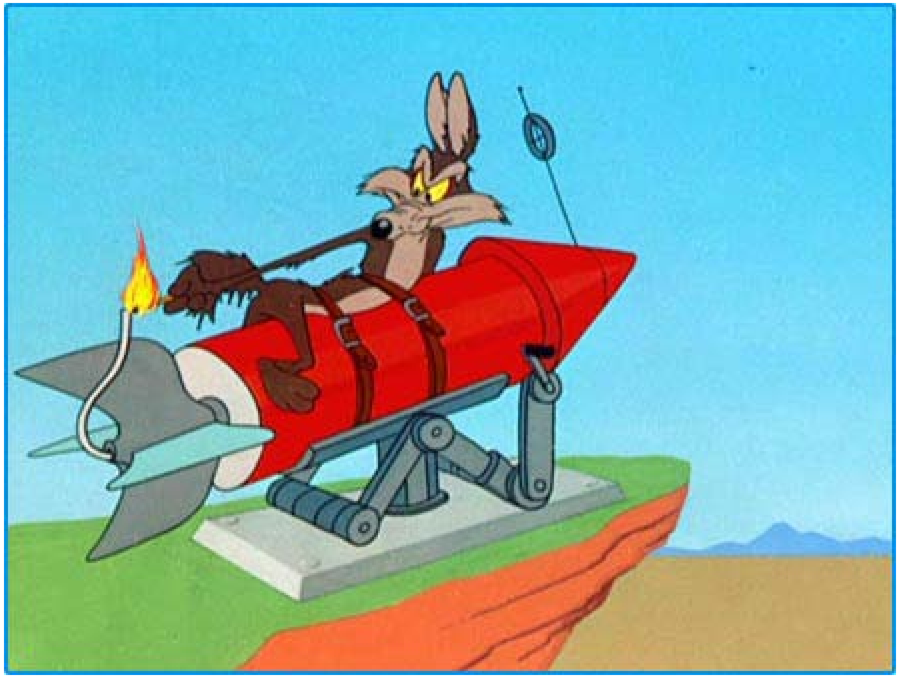
- Design, design, design ... and then implement
  - One Method not one size
  - Know the answer before you implement it, yes I know it takes out all the fun and equipoise but ...

- Simple counts ... A lot
  - Added effort these days equals non-compliance and poor results, integrate with workflow and dont expect it to adapt to you
- Robustness and 6x9 error
  - If the change you expect is within the 6x9 error you might get it needs to be either simpler (more robust) or avoided
  - Don't fool yourself on how large 6x9 error actually is ...

- All together, these are rare and hard to do, and require detailed on the ground insight and focused effort
  - It's why evolution so often beats revolution! In medicine as in many areas of engineering
  - Or, **keep your eye out for revolution while ensuring constant evolution** – it's how the biggest and best technology companies work (Truly! An iPhone is an iPod with a phone chip and an iPad is a large iPod!)

With special thanks to ...

- My occupational heroes...



- You’re never too old or experienced for a new take on gravity!